Food and Drug Administration, HHS

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 $[47\ FR\ 26823,\ June\ 22,\ 1982,\ as\ amended\ at\ 50\ FR\ 49536,\ Dec.\ 3,\ 1985;\ 63\ FR\ 66015,\ Dec.\ 1,\ 1998;\ 66\ FR\ 13847,\ Mar.\ 8,\ 2001]$

§ 172.160 Potassium nitrate.

The food additive potassium nitrate may be safely used as a curing agent in the processing of cod roe, in an amount not to exceed 200 parts per million of the finished roe.

§ 172.165 Quaternary ammonium chloride combination.

The food additive, quaternary ammonium chloride combination, may be safely used in food in accordance with the following conditions:

- (a) The additive contains the following compounds: *n*-dodecyl dimethyl benzyl ammonium chloride (CAS Reg. No. 139–07–1); *n*-dodecyl dimethyl ethylbenzyl ammonium chloride (CAS Reg. No. 27479–28–3); *n*-hexadecyl dimethyl benzyl ammonium chloride (CAS Reg. No. 122–18–9); *n*-octadecyl dimethyl benzyl ammonium chloride (CAS Reg. No. 122–19–0); *n*-tetradecyl dimethyl benzyl ammonium chloride (CAS Reg. No. 139–08–2); *n*-tetradecyl dimethyl ethylbenzyl ammonium chloride (CAS Reg. No. 27479–29–4).
- (b) The additive meets the following specifications: pH (5 percent active solution) 7.0–8.0; total amines, maximum 1 percent as combined free amines and amine hydrochlorides.
- (c) The additive is used as an antimicrobial agent, as defined in §170.3(o)(2) of this chapter, in raw sugar cane juice. It is added prior to clarification when further processing of the sugar cane juice must be delayed.
- (d) The additive is applied to the sugar juice in the following quantities, based on the weight of the raw cane:

| Component | Parts per million |
|---|----------------------|
| n-Dodecyl dimethyl benzyl ammonium chloride | 0.25-1.0 |

| Component | Parts per million |
|---|-------------------|
| n-Dodecyl dimethyl ethylbenzyl ammonium chloride | 3.4–13.5 |
| n-Hexadecyl dimethyl benzyl ammonium chlo- ride | 1.5–6.0 |
| n-Octadecyl dimethyl benzyl ammonium chlo- ride | 0.25–1.0 |
| n-Tetradecyl dimethyl benzyl ammonium chlo- ride | 3.0–12.0 |
| n-Tetradecyl dimethyl ethylbenzyl ammonium chloride | 1.6–6.5 |

[50 FR 3890, Jan. 29, 1985]

§ 172.170 Sodium nitrate.

The food additive sodium nitrate may be safely used in or on specified foods in accordance with the following prescribed conditions:

- (a) It is used or intended for use as follows:
- (1) As a preservative and color fixative, with or without sodium nitrite, in smoked, cured sablefish, smoked, cured salmon, and smoked, cured shad, so that the level of sodium nitrate does not exceed 500 parts per million and the level of sodium nitrite does not exceed 200 parts per million in the finished product.
- (2) As a preservative and color fixative, with or without sodium nitrite, in meat-curing preparations for the home curing of meat and meat products (including poultry and wild game), with directions for use which limit the amount of sodium nitrate to not more than 500 parts per million in the finished meat product and the amount of sodium nitrite to not more than 200 parts per million in the finished meat product.
- (b) To assure safe use of the additive, in addition to the other information required by the Act:
- (1) The label of the additive or of a mixture containing the additive shall bear:
- (i) The name of the additive.
- (ii) A statement of the concentration of the additive in any mixture.
- (2) If in a retail package intended for household use, the label and labeling of the additive, or of a mixture containing the additive, shall bear adequate directions for use to provide a final food product that complies with the limitations prescribed in paragraph (a) of this section.

§ 172.175

(3) If in a retail package intended for household use, the label of the additive or of a mixture containing the additive, shall bear the statement "Keep out of the reach of children".

§ 172.175 Sodium nitrite.

The food additive sodium nitrite may be safely used in or on specified foods in accordance with the following prescribed conditions:

- (a) It is used or intended for use as follows:
- (1) As a color fixative in smoked cured tunafish products so that the level of sodium nitrite does not exceed 10 parts per million (0.001 percent) in the finished product.
- (2) As a preservative and color fixative, with or without sodium nitrate, in smoked, cured sablefish, smoked, cured salmon, and smoked, cured shad so that the level of sodium nitrite does not exceed 200 parts per million and the level of sodium nitrate does not exceed 500 parts per million in the finished product.
- (3) As a preservative and color fixative, with sodium nitrate, in meat-curing preparations for the home curing of meat and meat products (including poultry and wild game), with directions for use which limit the amount of sodium nitrite to not more than 200 parts per million in the finished meat product, and the amount of sodium nitrate to not more than 500 parts per million in the finished meat product.
- (b) To assure safe use of the additive, in addition to the other information required by the Act:
- (1) The label of the additive or of a mixture containing the additive shall bear:
 - (i) The name of the additive.
- (ii) A statement of the concentration of the additive in any mixture.
- (2) If in a retail package intended for household use, the label and labeling of the additive, or of a mixture containing the additive, shall bear adequate directions for use to provide a final food product which complies with the limitations prescribed in paragraph (a) of this section.
- (3) If in a retail package intended for household use, the label of the additive, or of a mixture containing the ad-

ditive, shall bear the statement "Keep out of the reach of children".

§172.177 Sodium nitrite used in processing smoked chub.

The food additive sodium nitrite may be safely used in combination with salt (NaCl) to aid in inhibiting the outgrowth and toxin formation from *Clostridium botulinum* type E in the commercial processing of smoked chub in accordance with the following prescribed conditions:

- (a) All fish in smoking establishments shall be clean and wholesome and shall be expeditiously processed, packed, and stored under adequate sanitary conditions in accordance with good manufacturing practice.
- (b) The brining procedure is controlled in such a manner that the water phase portion of the edible portion of the finished smoked product has a salt (NaCl) content of not less than 3.5 percent, as measured in the loin muscle, and the sodium nitrite content of the edible portion of the finished smoked product is not less than 100 parts per million and not greater than 200 parts per million, as measured in the loin muscle.
- (c) Smoked chub shall be heated by a controlled heat process which provides a monitoring system positioned in as many strategic locations in the smokehouse as necessary to assure a continuous temperature throughout each fish of at least 160 °F for a minimum of 30 minutes.
- (d) The finished product shall be cooled to a temperature of 50 °F or below within 3 hours after smoking and further cooled to a temperature of 38 °F or below within 12 hours after smoking. A temperature of 38 °F or below shall be maintained during all subsequent storage and distribution. All shipping containers, retail packages, and shipping records shall indicate with appropriate notice the perishable nature of the product and specify that the product shall be held under refrigeration (38 °F or below) until consumed.
 - (e) To assure safe use of the additive:
- (1) The label and labeling of the additive container shall bear, in addition to the other information required by the Act, the name of the additive.